

REMARKS

Claims 1-44 are pending and claims 2-12, 22-27, and 31-44 are withdrawn from consideration. Claims 1, 13-21, and 28-30 stand rejected, claims 1, 2, and 5 have been amended, and claims 45-47 have been added. Applicants thank the Examiner for the consideration of Applicants' remarks with respect to the Van Tassel reference and for withdrawing the rejections under this reference.

Claim Rejections – 35 U.S.C. § 102

Claims 1 and 13-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,179,863 to Kensey et al. ("Kensey"). Applicants respectfully submit that amended claim 1 distinguishes over Kensey. Claim 1 recites a "first indicator coupled with the first inlet port, such that when the first inlet port penetrates a vessel the first indicator provides indication of excessive penetration of the insertion sheath to the vessel." Kensey does not teach or suggest an indicator that provides indication of excessive penetration of an insertion sheath to a vessel.

An indicator that indicates excessive penetration addresses problems associated with prior indicators. For example, one of the problems with prior indicators is the risk of over insertion. Over insertion may occur when "[p]roper depth of penetration and location of the assembly is established by continuing [after blood starts flowing from the driphole] to insert an additional distance, for example, . . . 1 to 2 centimeters." *Specification, page 2*. Thus, over insertion may occur when a physician needs to insert an assembly 1 to 2 centimeters further after blood begins to flow from the driphole, leaving the physician uncertain of whether or not the assembly is over inserted.

The specification explains how this problem may be addressed: “[I]n use, assembly 400 would first be inserted until vessel penetration was indicated, as with the prior art device above. Using the prior art device, care must be exercised during reinsertion of the assembly approximately 1 to 2 centimeters to ensure it is not over inserted. Using assembly 400, however, over insertion indicator port 420 would provide over insertion indication when blood begins flowing from over insertion drip hole 422, thereby assisting proper location of assembly 400 and avoiding over insertion.” *Page 5*. Thus, by reciting a “first indicator [that] provides indication of too far penetration of the insertion sheath to the vessel,” claim 1 addresses at least one problem (*i.e.*, over insertion) associated with prior indicators.

Kensey does not address the problem of over insertion. Indeed, Kensey’s indicators suffer from the same problem that the specification notes in other prior indicators. According to Kensey,

The positioning of the introducer sheath . . . is similar to that described with reference to the device 200. Thus, after the introducer sheath is positioned as described earlier the stopcock 28E is opened to observe the flow of blood therefrom The introducer sheath is then retracted (moved proximally) until the blood flow through the stop-cock just stops . . . The introducer sheath with the device therein is then reinserted approximately 10 mm [1 cm] into the puncture to ensure that the distal end of introducer sheath is at the desired position within the artery.

Column 11, lines 25-39. Thus, a physician using Kensey’s device, just like a physician using the prior devices described in the specification, establishes depth of penetration and location of the assembly by continuing to insert the device an additional 1 to 2 centimeters after receiving an indication. As previously mentioned, inserting the device 1 to 2 centimeters after receiving an indication risks over insertion. Thus, Kensey does not show, teach, or suggest an indicator that provides indication of excessive penetration of the insertion sheath to the vessel.

Since Kensey fails to teach or suggest an indicator that provides indication of excessive penetration, Kensey fails to anticipate claim 1. Accordingly, independent claim 1, as well as claims 13-16, which depend from claim 1, are allowable over Kensey. Applicants therefore request withdrawal of the rejections based on 35 U.S.C. § 102(b) and submit that claims 1 and 13-16 are in condition for allowance.

Claim Rejections – 35 U.S.C. § 103

Claims 17-21 and 28-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kensey. Claim 28 recites a vascular insertion assembly with “a first inlet port located about the dilator distal end and a second inlet port located about the sheath distal end.” The Office Action states,

Kensey fails to disclose an embodiment including a first inlet port in the dilator and a second inlet port in the insertion sheath. Kensey does disclose both locations of inlet ports but in separate embodiments. The introducer sheaths of Figures 27 and 31 with inlet ports are capable of receiving the dilator of Figure 29 with an inlet port. One of ordinary skill in the art would be capable of providing a second drip hole when combining the structures. This modification would involve only routine skill in the art [and] would increase the versatility of the components by allowing the user multiple modes of identifying blood vessel location.

Page 3. Applicants traverse this rejection.

The Examiner does not establish a *prima facie* case of obviousness because the Examiner does not set forth adequate motivation to modify Kensey to provide the features of claim 1. The Examiner asserts that the modification of Kensey “would increase the versatility of the components by allowing the user multiple modes of identifying blood vessel location.” However, Kensey does not show, teach, or suggest that combining the dilator and sheath input ports in a single device would provide multiple modes of identifying blood vessel location.

Modifying Kensey as suggested by the Examiner would result in a more complex device, but would not provide any apparent advantages. For example, combining the sheath and dilator openings in a single device would only provide a single mode, not multiple modes, of identifying blood vessel location. In discussing the dilator opening embodiment, Kensey states:

[O]nce the flow of blood is observed the introducer sheath with the device therein is then retracted (moved proximally) until the blood flow through the stopcock just stops, a position shown in FIG. 13. This indicates that the distal end 28C of the introducer sheath has just left the artery lumen. The introducer sheath with the device therein is then reinserted approximately 10 mm into the puncture to ensure that the distal end of introducer sheath is at the desired position within the artery.

Column 10, lines 5-14. The description of the positioning of the sheath opening embodiment is almost identical to the description of the dilator opening embodiment:

Thus, after the introducer sheath is positioned as described earlier the stopcock 28E is opened to observe the flow of blood therefrom (thereby indicating that the inlet port or window is within the artery). The introducer sheath is then retracted (moved proximally) until the blood flow through the stopcock just stops, thereby indicating that the distal end 28C of the introducer sheath has just left the artery lumen. The introducer sheath with the device therein is then reinserted approximately 10 mm into the puncture to ensure that the distal end of introducer sheath is at the desired position within the artery.

Column 11, lines 28-39. In both cases, when the blood flow stops, it indicates that the distal end 28C of the introducer sheath has just left the artery. Thus, both the sheath and the dilator indicators of Kensey provide the same information—they indicate “that the distal end 28C of the introducer sheath has just left the artery lumen.” *Col. 10 and Col. 11.*

In view of the foregoing portions of Kensey’s specification, Kensey teaches only one mode of identifying a blood vessel location, not two modes as suggested by the Examiner. Accordingly, combining the sheath indicator and dilator indicator embodiments does not provide the advantage suggested by the Examiner. In fact, combining the dilator and sheath indicators

would probably add complexity to Kensey's device without providing a user any additional location information.

Thus, the Examiner has failed to show any motivation in the art for modifying Kensey to provide the features of claim 28. According to the Federal Circuit, it is error to reach a conclusion of obviousness "without any specific hint or suggestion in a particular reference." *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). Indeed, the Federal Circuit cautioned that an obviousness analysis that does not show such a suggestion "simply takes the inventor's disclosure as a blueprint for piecing together prior art to defeat patentability—the essence of hindsight." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Cited references, such as Kensey, must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136 (Fed. Cir. 1986). Applicants recognize that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971). However, hindsight reasoning is only proper "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure." *Id.* The Examiner appears to provide a hindsight analysis by looking to the invention, rather than the prior art, to find motivation for modifying Kensey.

In *Dembiczak*, the Federal Circuit suggested that the Examiner should take special precautions against hindsight reasoning when the technology is not highly complex or difficult to understand. 175 F.3d 999. The invented technology in *Dembiczak* was a trash bag that resembled a jack-o-lantern. *Id.* Like *Dembiczak*, the present application does not involve highly

complex technology. In fact, the Examiner suggests that modifying Kensey to provide the features of claim 28 “would involve only routine skill in the art.” The Federal Circuit made it clear that preventing rejections based on hindsight reconstruction “is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’” *Id.* (quoting *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)). The Examiner does not point to any specific hint or suggestion in Kensey for modifying the claims and therefore fails to take these special precautions against hindsight reasoning. Thus, the Examiner fails provide motivation to modify Kensey without using improper hindsight reasoning. Accordingly, the Examiner has not established a *prima facie* case of obviousness.

Even if the Examiner were to somehow find adequate motivation to modify Kensey (which Applicants have shown is not the case), if Kensey were modified as suggested by the Examiner, the result of the modification fails to render obvious the claimed invention and fails to provide the advantages of the claimed invention. This is because, as previously noted, combining the dilator and sheath indicator embodiments of Kensey would add complexity to Kensey’s device without providing any advantages over either embodiment take alone.

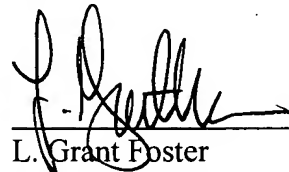
Therefore, claim 28 is not taught or suggested by Kensey, and is therefore not obvious. The foregoing arguments apply with equal force to claim 17. Accordingly, claims 17 and 28, as well as claims 18-21, 29, and 30 which depend from claims 17 and 28, are allowable over Kensey. Applicants therefore request withdrawal of the rejections based on 35 U.S.C. § 103(a) and submit that claims 17-21 and 28-30 are in condition for allowance.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. Applicants request reconsideration and allowance of the pending claims. Applicants invite the Examiner to contact the undersigned by telephone if there remain unresolved issues to expedite prosecution of the present application.

Respectfully submitted,

Dated: 13 NOVEMBER 2006



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